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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/887,296	06/21/2001	Hsien-Jue (Steve) Chu	AM100221	6853

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EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 06/25/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/887,296

Applicant(s)

Chu et al.

Examiner

S. Devi, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 11, 2003
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 ~~is/are~~ pending in the application.
- 4a) Of the above, claim(s) 11-26 ~~is/are~~ withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 27-30 ~~is/are~~ rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. _____.
- ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- ☐ Interview Summary (PTO-413) Paper No(s). _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other:

RESPONSE TO APPLICANTS' AMENDMENT

Applicants' Amendment

- 1) Acknowledgment is made of Applicants' amendment filed 04/11/03 (paper no. 8) in response to the non-final Office Action mailed 02/14/03 (paper no. 7).

Status of Claims

- 2) Claims 1-3 and 10 have been amended via the amendment filed 04/11/03.
New claims 27-30 have been added via the amendment filed 04/11/03.
Claims 1-30 are pending.
Claims 1-10 and 27-30 are under examination.

Prior Citation of Title 35 Sections

- 3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

- 4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Objection(s) Withdrawn

- 5) The objection to the abstract made in paragraph 5 of the Office Action mailed 02/14/03 (paper no. 7) is withdrawn in light of Applicants' amendment to the abstract.
6) The objection to the specification made in paragraph 6(a) of the Office Action mailed 02/14/03 (paper no. 7) is withdrawn in light of Applicants' amendment to the specification.
7) The objection to the specification made in paragraph 6(b) of the Office Action mailed 02/14/03 (paper no. 7) is withdrawn in light of Applicants' amendment to the specification.

Rejection(s) Withdrawn

- 8) The rejection of claim 1 made in paragraph 7(a) of the Office Action mailed 02/14/03 (paper no. 7) under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to claim 1.
9) The rejection of claim 1 made in paragraph 7(b) of the Office Action mailed 02/14/03 (paper no. 7) under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of

Applicants' amendment to claim 1.

10) The rejection of claim 1 made in paragraph 7(c) of the Office Action mailed 02/14/03 (paper no. 7) under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to claim 1.

11) The rejection of claim 2 made in paragraph 7(d) of the Office Action mailed 02/14/03 (paper no. 7) under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to claim 2.

12) The rejection of claim 3 made in paragraph 7(e) of the Office Action mailed 02/14/03 (paper no. 7) under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to claim 1.

13) The rejection of claim 3 made in paragraph 7(f) of the Office Action mailed 02/14/03 (paper no. 7) under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to claim 3.

14) The rejection of claim 3 made in paragraph 7(g) of the Office Action mailed 02/14/03 (paper no. 7) under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to claim 3.

15) The rejection of claim 10 made in paragraph 7(h) of the Office Action mailed 02/14/03 (paper no. 7) under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to claim 10.

16) The rejection of claims 2-10 made in paragraph 7(j) of the Office Action mailed 02/14/03 (paper no. 7) under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the base claim.

17) The rejection of claim 1 made in paragraph 9 of the Office Action mailed 02/14/03 (paper no. 7) under 35 U.S.C § 102(e) as being anticipated by Heo *et al.* (US 6,491,956) as evidenced by Bakal *et al.* (US 4,414,229), is withdrawn in light of Applicants' amendment to the claim.

18) The rejection of claims 1-3, 5 and 6 made in paragraph 10 of the Office Action mailed 02/14/03 (paper no. 7) under 35 U.S.C § 102(e) as being anticipated by Casas *et al.* (US 6,100,388) as evidenced by Bakal *et al.* (US 4,414,229), is withdrawn in light of Applicants' amendment to the base claim.

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- 19) The rejection of claims 1-3, 5, 6 and 9 made in paragraph 11 of the Office Action mailed 02/14/03 (paper no. 7) under 35 U.S.C § 102(e) as being anticipated by Clements *et al.* (US 6,019,982) as evidenced by Bakal *et al.* (US 4,414,229), is withdrawn in light of Applicants' amendment to the base claim.
- 20) The rejection of claims 1, 4, 6 and 7 made in paragraph 13 of the Office Action mailed 02/14/03 (paper no. 7) under 35 U.S.C § 103(a) as being unpatentable over Casas *et al.* (US 6,100,388) or Clements *et al.* (US 6,019,982) in view of Grieve (*Poultry Digest*, November 1992, pp. 28-32 - Applicants' IDS), is withdrawn in light of Applicants' amendment to the base claim.
- 21) The rejection of claim 10 made in paragraph 14 of the Office Action mailed 02/14/03 (paper no. 7) under 35 U.S.C § 103(a) as being unpatentable over Casas *et al.* (US 6,100,388) or Clements *et al.* (US 6,019,982) as modified by Grieve (*Poultry Digest*, November 1992, pp. 28-32 - Applicants' IDS) as applied to claims 1, 6 and 7 above, and further in view of Roland (US 6,399,074), is withdrawn in light of Applicants' amendment to the base claim.
- 22) The rejection of claim 8 made in paragraph 15 of the Office Action mailed 02/14/03 (paper no. 7) under 35 U.S.C § 103(a) as being unpatentable over Clements *et al.* (US 6,019,982) as modified by Grieve (*Poultry Digest*, November 1992, pp. 28-32 - Applicants' IDS) as applied to claims 1, 6 and 7 above, and further in view of Frantz *et al.* (US 5,536,496), is withdrawn in light of Applicants' amendment to the base claim.

Rejection(s) Maintained

- 23) The rejection of claim 3 made in paragraph 7(i) of the Office Action mailed 02/14/03 (paper no. 7) under 35 U.S.C § 112, second paragraph, as being indefinite, is maintained for reasons set forth therein.

New Rejection(s)

Applicants are asked to note the following new rejection(s) made in this Office. The new rejections are necessitated by Applicants' amendments to the claims and/or the submission of new claims.

Rejection(s) under 35 U.S.C. 112, Second Paragraph

- 24) Claim 3 is rejected under 35 U.S.C § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the

invention.

Claim 3 is incorrect and confusing in the recitation: "*choleraeausis*". The correct recitation should be --*choleraeausis*--.

Rejection(s) under 35 U.S.C. 103

25) Claims 1, 29 and 30 are rejected under 35 U.S.C § 103(a) as being unpatentable over Heo *et al.* (US 6,491,956, already of record) in view of the DE patent 1793631, Shimada *et al.* (US 5,626,837) and Cederholm-Williams (US 2002/0064517 A1).

The reference of Cederholm-Williams is used in this rejection since it qualifies as prior art under 35 U.S.C § 102(e)1, and accordingly is not disqualified under 35 U.S.C § 103.

Heo *et al.* disclosed a method of preventing and/or treating (i.e., protecting) *H. pylori* infection in a human by administering a composition comprising an effective amount of a bacterial antigen, *Lactobacillus acidophilus*, which is produced by admixing the bacterial antigen, *Lactobacillus acidophilus*, with a water soluble vehicle. The composition is a fortified liquid drinkable yogurt, buttermilk, cream cheese or ice cream (i.e., orally administered vaccine) containing water-soluble glucose, dextrose, fructose, lactose etc. See paragraph bridging columns 5 and 6; first and second full paragraphs in column 5; and first full paragraph in column 8.

That the 'human' described in the primary reference qualifies as an animal is implicit from the teachings Heo *et al.* in light of what is well known in the art. For instance, Cederholm-Williams taught the recognition in the art of a human as a mammalian animal (see section 0073).

Heo *et al.* are silent about the presence of a flavorant, such as a strawberry flavorant, in their fortified icecream or yoghurt comprising the bacterial antigen.

However, the use of a strawberry-flavored ice-cream or yoghurt was known, and such a product was available in the art at the time of the invention. For example, the patent DE 1793631 taught the routine and conventional addition of a strawberry flavor to ice-cream, yoghurt and milk drinks for the purpose of imparting strawberry taste to these foods. The patent DE 1793631 taught ice-cream, yoghurt and milk drinks containing a strawberry flavoring agent (see abstract). That the strawberry flavorant used in the flavored ice-cream, yoghurt and milk drinks described by the patent DE 1793631 is intrinsically water soluble is implicit from the disclosure of the patent in light of what was known in the art. For instance, Shimada *et al.* expressly taught the strawberry flavorant to be

water soluble (see claims and Table in columns 11 and 12, particularly line 8 in column 12).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to replace Heo's ice cream or yoghurt with the DE 1793631 patented strawberry-flavored ice-cream or yoghurt to produce the instant invention, with a reasonable expectation of success. One of skill in the art would have been motivated to produce the instant invention for the expected benefit of imparting a strawberry taste to Heo's ice cream or yoghurt, since the use of such taste-improving fruit-flavored food products were well known in the art at the time of the invention as taught by the patent DE 1793631.

Claims 1, 29 and 30 are *prima facie* obvious over the prior art of record.

26) Claims 1-3, 5, 6, 29 and 30 are rejected under 35 U.S.C § 103(a) as being unpatentable over Casas *et al.* (US 6,100,388, already of record) in view of the DE patent 1793631 and Shimada *et al.* (US 5,626,837).

Casas *et al.* disclosed a method of vaccinating an animal for beneficially preventing, treating or protecting a diarrhoeal disease comprising administering said animal an orally administered *L. reuteri* vaccine expressing an antigen of enterotoxigenic *E. coli*, for example, K88 *E. coli*, a porcine pathogen. The vaccine is produced by combining the bacterial cells with a pharmaceutically acceptable excipient or a food product such as milk or yogurt for oral administration. The animal is an avian animal, i.e., inclusive of poultry. The method can be used in pharmaceutical and food industries for vaccination against pathogenic microorganisms. The vaccine is ingested by an animal in a pharmaceutically acceptable carrier or can be added to milk or milk products such as yogurt. See column 5, first full paragraph and lines 40-44; third full paragraph in column 4; column 12, lines 35-43; paragraphs bridging columns 4 and 5, columns 5 and 6, columns 14 and 15, and columns 15 and 16; Example II.

Casas *et al.* are silent about the presence of a flavorant, such as a strawberry flavorant, in their icecream or yoghurt comprising the orally administered vaccine.

However, the use of a strawberry-flavored milk or yoghurt was known and such a product was available in the art at the time of the invention. For example, patent DE 1793631 taught the routine and conventional addition of a strawberry flavor to ice-cream, yoghurt and milk drinks for the purpose of imparting strawberry taste to these foods. The patent DE 1793631 taught yoghurt

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and milk drinks containing a strawberry flavoring agent (see abstract). That the strawberry flavorant used in the flavored yoghurt and milk drinks described by the patent DE 1793631 is intrinsically water soluble is implicit from the disclosure of the patent in light of what was known in the art. For instance, Shimada *et al.* expressly taught the strawberry flavorant to be water soluble (see claims and Table in columns 11 and 12, particularly line 8 in column 12).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to replace Casas's milk or yoghurt with the DE 1793631 patented strawberry-flavored milk or yoghurt to produce the instant invention, with a reasonable expectation of success. One of skill in the art would have been motivated to produce the instant invention for the expected benefit of imparting a strawberry taste to Casas's milk or yoghurt, since the use of such taste-improving fruit-flavored food products were well known in the art at the time of the invention as taught by the patent DE 1793631.

Claims 1-3, 5, 6, 29 and 30 are *prima facie* obvious over the prior art of record.

27) Claims 1-3, 5, 6, 9, 29 and 30 are rejected under 35 U.S.C § 103(a) as being unpatentable over Clements *et al.* (US 6,019,982, already of record) in view of the DE patent 1793631 and Shimada *et al.* (US 5,626,837).

Clements *et al.* disclosed a method of providing protection against an enterotoxigenic bacterial pathogen, such as, *Escherichia coli*, by administering an oral vaccine composition comprising the killed or attenuated whole cells of the pathogen and/or a mutant heat-labile enterotoxin. The vaccine comprises a microbial protective antigen such as *Escherichia coli* (a poultry pathogen), *Borrelia burgdorferi* (a canine pathogen), *Clostridium tetani*, *Salmonella typhimurium* (a poultry pathogen), *Brucella suis* (a porcine pathogen), *Leptospira icterohaemorrhagiae*, *Mycoplasma* sps. or parainfluenza virus, Reo virus, Parvo virus, or respiratory syncytial virus etc., The method is used in birds, immature and mature vertebrates, animal species, mammals and humans. The antigen composition is produced by combining the antigen(s) with a liquid pharmaceutical carrier and a palatable flavoring agent for oral administration. The vaccine is further reconstituted with a substance such as milk. See sections 5 and 5.2 of the patent, particularly in columns 9-14 and fifth and sixth full paragraphs in column 4. That Clements' 'birds' are inclusive of poultry and that Clements' 'vertebrates' or 'animal species' are inclusive of swine or dogs is inherent from the

teachings of Clements *et al.* since it is well known in the art that Clements' antigens, such as, *Salmonella typhimurium* or *Escherichia coli* are art-known poultry, swine or canine pathogens, *Borrelia burgdorferi* is an art-known canine pathogen, and *Brucella suis* is a art-known swine pathogen.

Clements *et al.* are silent about the presence of a flavorant, such as a strawberry flavorant, in their oral composition reconstituted with milk.

However, the use of a strawberry-flavored milk or yoghurt was known and available in the art at the time of the invention. For example, patent DE 1793631 taught the routine and conventional addition of a strawberry flavor to and milk drinks to impart strawberry taste to these foods. The patent DE 1793631 taught milk drinks containing a strawberry flavoring agent (see abstract). That the strawberry flavorant used in the flavored milk drinks described by the patent DE 1793631 is intrinsically water soluble is implicit from the disclosure of the patent in light of what is known in the art. For instance, Shimada *et al.* taught the strawberry flavorant to be water soluble (see claims and Table in columns 11 and 12, particularly line 8 in column 12).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to replace Clements's milk with the DE 1793631 patented strawberry-flavored milk to produce the instant invention, with a reasonable expectation of success. One of skill in the art would have been motivated to produce the instant invention for the expected benefit of imparting a strawberry taste to Clements's milk, since the use of such taste-improving fruit-flavored food products were well known in the art at the time of the invention as taught by the patent DE 1793631.

Claims 1-3, 5, 6, 9, 29 and 30 are *prima facie* obvious over the prior art of record.

28) Claims 4, 7, 27 and 28 are rejected under 35 U.S.C § 103(a) as being unpatentable over Casas *et al.* (US 6,100,388, already of record) or Clements *et al.* (US 6,019,982, already of record) as modified by the DE patent 1793631 and Shimada *et al.* (US 5,626,837) as applied to claims 1 and 4 above, and further in view of Grieve (*Poultry Digest*, November 1992, pp. 28-32, already of record).

The teachings of Casas *et al.* or Clements *et al.* as modified by the DE patent 1793631 and Shimada *et al.* are explained above, which do not disclose the administration of the vaccine through drinking water.

However, it was routine at the time of the instant invention to carry out mass vaccination of poultry via drinking water. For instance, Grieve taught the routine, economical and time-effective mass vaccination of poultry through drinking water (see page 28).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to carry out Casas's or Clements' method of providing protection to poultry birds as modified by the DE patent 1793631 and Shimada *et al.* via drinking water vehicle as taught by Grieve to produce the instant invention with a reasonable expectation of success, since Grieve showed it to be conventional, routine, economical and time-effective to administer a vaccine to poultry birds via drinking water. Choosing one art-known administration route or vehicle over another route or vehicle would have been obvious and was well within the realm of routine experimentation. One of skill in the art would have readily understood that administration of a vaccine via drinking water for mass vaccination is a matter of convenience, economy and time effectiveness.

Claims 4, 7, 27 and 28 are *prima facie* obvious over the prior art of record.

29) Claim 10 is rejected under 35 U.S.C § 103(a) as being unpatentable over Casas *et al.* (US 6,100,388, already of record) or Clements *et al.* (US 6,019,982, already of record) as modified by the DE patent 1793631, Shimada *et al.* (US 5,626,837) and Grieve (*Poultry Digest*, November 1992, pp. 28-32, already of record) as applied to claims 1, 6 and 7 above, and further in view of Roland (US 6,399,074, already of record).

The reference of Roland is applied in this rejection because it qualifies as prior art under subsection (e) of 35 U.S.C § 102 and accordingly is not disqualified under U.S.C 103(a).

The teachings of Casas *et al.* or Clements *et al.* as modified by the DE patent 1793631, Shimada *et al.* and Grieve are explained above, which do not disclose the administration of the vaccine into the mouth through a syringe.

However, it was routine at the time of the instant invention to use a syringe for oral administration or vaccination of birds. For instance, Roland taught such a routine procedure (see lines 20-22 in column 18)

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to carry out Casas's or Clements' method as modified by the DE patent

1793631, Shimada *et al.* and Grieve in poultry using Roland's feeding syringe to produce the instant invention with a reasonable expectation of success, since Roland has shown it to be conventional and routine to administer a vaccine orally to birds using a syringe. Choosing one art-known administration method over another would have been obvious and is well within the realm of routine experimentation. One of skill in the art would have readily understood that oral administration of a vaccine using a syringe is a matter of convenience.

Claim 10 is *prima facie* obvious over the prior art of record.

30) Claim 8 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Clements *et al.* (US 6,019,982) as modified by the DE patent 1793631, Shimada *et al.* (US 5,626,837) and Grieve (*Poultry Digest*, November 1992, pp. 28-32, already of record) as applied to claims 1, 6 and 7 above, and further in view of Frantz *et al.* (US 5,536,496, already of record).

The teachings of Clements *et al.* as modified by the DE patent 1793631, Shimada *et al.* and Grieve are explained above, which do not disclose the administration of *Erysipelothrix rhusiopathiae*-containing vaccine.

However, Clements *et al.* taught that their vaccine may contain and be administered with any biologically relevant antigen and/or vaccine, or killed or attenuated pathogens or relevant virulence determinants (i.e., antigens) of specific pathogens. See paragraph bridging columns 9 and 10; and paragraph bridging columns 11 and 12.

Frantz *et al.* disclosed an *Erysipelothrix rhusiopathiae* bacterin or vaccine which is administered by any mode of administration or by any suitable route. The vaccine protected pigs from a challenge infection. See columns 20 and 21; see first full paragraph in column 5; and paragraph bridging columns 5 and 6.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use Frantz's *Erysipelothrix rhusiopathiae* bacterin or protective vaccine in Clements' method as modified by the DE patent 1793631, Shimada *et al.* and Grieve to produce the instant invention with a reasonable expectation of success, since Clements *et al.* expressly taught that any biologically relevant antigen and/or vaccine, or killed or attenuated pathogens or relevant virulence determinants (i.e., antigens) of a specific pathogen can be used in their method. Given the teaching of Frantz *et al.* that their *Erysipelothrix rhusiopathiae* bacterin or protective vaccine is

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administered by any mode of administration or by any suitable route, one of skill in the art would have been motivated to produce the instant invention for the expected benefit of providing protection against *Erysipelothrix rhusiopathiae* disease in pigs or immature piglets.

Claim 8 is *prima facie* obvious over the prior art of record.

Relevant Prior Art

31) The prior art made of record and not relied upon currently in any of the rejections is considered pertinent to Applicants' disclosure:

- Chen *et al.* (US 2003/0068378 A1, filed January 1999) taught that the cherry, strawberry and watermelon flavoring agents are water soluble extracts (see section 0040).

Remarks

32) Claims 1-10 and 27-30 stand rejected.

33) Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

34) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1 (CM1). The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone number is (703) 308-4242, which receives papers 24 hours a day and seven days a week. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

35) Any inquiry concerning this communication or earlier communications from the Examiner

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should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

June, 2003

RESPONSE TO APPLICANTS' AMENDMENT

Applicants' Amendment

- 1) Acknowledgment is made of Applicants' amendment filed 04/11/03 (paper no. 8) in response to the non-final Office Action mailed 02/14/03 (paper no. 7).

Status of Claims

- 2) Claims 1-3 and 10 have been amended via the amendment filed 04/11/03.
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Prior Citation of Title 35 Sections

- 3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

- 4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Objection(s) Withdrawn

- 5) The objection to the abstract made in paragraph 5 of the Office Action mailed 02/14/03 (paper no. 7) is withdrawn in light of Applicants' amendment to the abstract.
6) The objection to the specification made in paragraph 6(a) of the Office Action mailed 02/14/03 (paper no. 7) is withdrawn in light of Applicants' amendment to the specification.
7) The objection to the specification made in paragraph 6(b) of the Office Action mailed 02/14/03 (paper no. 7) is withdrawn in light of Applicants' amendment to the specification.

Rejection(s) Withdrawn

- 8) The rejection of claim 1 made in paragraph 7(a) of the Office Action mailed 02/14/03 (paper no. 7) under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to claim 1.
9) The rejection of claim 1 made in paragraph 7(b) of the Office Action mailed 02/14/03 (paper no. 7) under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of

Applicants' amendment to claim 1.

10) The rejection of claim 1 made in paragraph 7(c) of the Office Action mailed 02/14/03 (paper no. 7) under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to claim 1.

11) The rejection of claim 2 made in paragraph 7(d) of the Office Action mailed 02/14/03 (paper no. 7) under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to claim 2.

12) The rejection of claim 3 made in paragraph 7(e) of the Office Action mailed 02/14/03 (paper no. 7) under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to claim 1.

13) The rejection of claim 3 made in paragraph 7(f) of the Office Action mailed 02/14/03 (paper no. 7) under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to claim 3.

14) The rejection of claim 3 made in paragraph 7(g) of the Office Action mailed 02/14/03 (paper no. 7) under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to claim 3.

15) The rejection of claim 10 made in paragraph 7(h) of the Office Action mailed 02/14/03 (paper no. 7) under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to claim 10.

16) The rejection of claims 2-10 made in paragraph 7(j) of the Office Action mailed 02/14/03 (paper no. 7) under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the base claim.

17) The rejection of claim 1 made in paragraph 9 of the Office Action mailed 02/14/03 (paper no. 7) under 35 U.S.C § 102(e) as being anticipated by Heo *et al.* (US 6,491,956) as evidenced by Bakal *et al.* (US 4,414,229), is withdrawn in light of Applicants' amendment to the claim.

18) The rejection of claims 1-3, 5 and 6 made in paragraph 10 of the Office Action mailed 02/14/03 (paper no. 7) under 35 U.S.C § 102(e) as being anticipated by Casas *et al.* (US 6,100,388) as evidenced by Bakal *et al.* (US 4,414,229), is withdrawn in light of Applicants' amendment to the base claim.

- 19) The rejection of claims 1-3, 5, 6 and 9 made in paragraph 11 of the Office Action mailed 02/14/03 (paper no. 7) under 35 U.S.C § 102(e) as being anticipated by Clements *et al.* (US 6,019,982) as evidenced by Bakal *et al.* (US 4,414,229), is withdrawn in light of Applicants' amendment to the base claim.
- 20) The rejection of claims 1, 4, 6 and 7 made in paragraph 13 of the Office Action mailed 02/14/03 (paper no. 7) under 35 U.S.C § 103(a) as being unpatentable over Casas *et al.* (US 6,100,388) or Clements *et al.* (US 6,019,982) in view of Grieve (*Poultry Digest*, November 1992, pp. 28-32 - Applicants' IDS), is withdrawn in light of Applicants' amendment to the base claim.
- 21) The rejection of claim 10 made in paragraph 14 of the Office Action mailed 02/14/03 (paper no. 7) under 35 U.S.C § 103(a) as being unpatentable over Casas *et al.* (US 6,100,388) or Clements *et al.* (US 6,019,982) as modified by Grieve (*Poultry Digest*, November 1992, pp. 28-32 - Applicants' IDS) as applied to claims 1, 6 and 7 above, and further in view of Roland (US 6,399,074), is withdrawn in light of Applicants' amendment to the base claim.
- 22) The rejection of claim 8 made in paragraph 15 of the Office Action mailed 02/14/03 (paper no. 7) under 35 U.S.C § 103(a) as being unpatentable over Clements *et al.* (US 6,019,982) as modified by Grieve (*Poultry Digest*, November 1992, pp. 28-32 - Applicants' IDS) as applied to claims 1, 6 and 7 above, and further in view of Frantz *et al.* (US 5,536,496), is withdrawn in light of Applicants' amendment to the base claim.

Rejection(s) Maintained

- 23) The rejection of claim 3 made in paragraph 7(i) of the Office Action mailed 02/14/03 (paper no. 7) under 35 U.S.C § 112, second paragraph, as being indefinite, is maintained for reasons set forth therein.

New Rejection(s)

Applicants are asked to note the following new rejection(s) made in this Office. The new rejections are necessitated by Applicants' amendments to the claims and/or the submission of new claims.

Rejection(s) under 35 U.S.C. 112, Second Paragraph

- 24) Claim 3 is rejected under 35 U.S.C § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the

invention.

Claim 3 is incorrect and confusing in the recitation: "*choleraeausis*". The correct recitation should be --*choleraeausis*--.

Rejection(s) under 35 U.S.C. 103

25) Claims 1, 29 and 30 are rejected under 35 U.S.C § 103(a) as being unpatentable over Heo *et al.* (US 6,491,956, already of record) in view of the DE patent 1793631, Shimada *et al.* (US 5,626,837) and Cederholm-Williams (US 2002/0064517 A1).

The reference of Cederholm-Williams is used in this rejection since it qualifies as prior art under 35 U.S.C § 102(e)1, and accordingly is not disqualified under 35 U.S.C § 103.

Heo *et al.* disclosed a method of preventing and/or treating (i.e., protecting) *H. pylori* infection in a human by administering a composition comprising an effective amount of a bacterial antigen, *Lactobacillus acidophilus*, which is produced by admixing the bacterial antigen, *Lactobacillus acidophilus*, with a water soluble vehicle. The composition is a fortified liquid drinkable yogurt, buttermilk, cream cheese or ice cream (i.e., orally administered vaccine) containing water-soluble glucose, dextrose, fructose, lactose etc. See paragraph bridging columns 5 and 6; first and second full paragraphs in column 5; and first full paragraph in column 8.

That the 'human' described in the primary reference qualifies as an animal is implicit from the teachings Heo *et al.* in light of what is well known in the art. For instance, Cederholm-Williams taught the recognition in the art of a human as a mammalian animal (see section 0073).

Heo *et al.* are silent about the presence of a flavorant, such as a strawberry flavorant, in their fortified icecream or yoghurt comprising the bacterial antigen.

However, the use of a strawberry-flavored ice-cream or yoghurt was known, and such a product was available in the art at the time of the invention. For example, the patent DE 1793631 taught the routine and conventional addition of a strawberry flavor to ice-cream, yoghurt and milk drinks for the purpose of imparting strawberry taste to these foods. The patent DE 1793631 taught ice-cream, yoghurt and milk drinks containing a strawberry flavoring agent (see abstract). That the strawberry flavorant used in the flavored ice-cream, yoghurt and milk drinks described by the patent DE 1793631 is intrinsically water soluble is implicit from the disclosure of the patent in light of what was known in the art. For instance, Shimada *et al.* expressly taught the strawberry flavorant to be

water soluble (see claims and Table in columns 11 and 12, particularly line 8 in column 12).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to replace Heo's ice cream or yoghurt with the DE 1793631 patented strawberry-flavored ice-cream or yoghurt to produce the instant invention, with a reasonable expectation of success. One of skill in the art would have been motivated to produce the instant invention for the expected benefit of imparting a strawberry taste to Heo's ice cream or yoghurt, since the use of such taste-improving fruit-flavored food products were well known in the art at the time of the invention as taught by the patent DE 1793631.

Claims 1, 29 and 30 are *prima facie* obvious over the prior art of record.

26) Claims 1-3, 5, 6, 29 and 30 are rejected under 35 U.S.C § 103(a) as being unpatentable over Casas *et al.* (US 6,100,388, already of record) in view of the DE patent 1793631 and Shimada *et al.* (US 5,626,837).

Casas *et al.* disclosed a method of vaccinating an animal for beneficially preventing, treating or protecting a diarrhoeal disease comprising administering said animal an orally administered *L. reuteri* vaccine expressing an antigen of enterotoxigenic *E. coli*, for example, K88 *E. coli*, a porcine pathogen. The vaccine is produced by combining the bacterial cells with a pharmaceutically acceptable excipient or a food product such as milk or yogurt for oral administration. The animal is an avian animal, i.e., inclusive of poultry. The method can be used in pharmaceutical and food industries for vaccination against pathogenic microorganisms. The vaccine is ingested by an animal in a pharmaceutically acceptable carrier or can be added to milk or milk products such as yogurt. See column 5, first full paragraph and lines 40-44; third full paragraph in column 4; column 12, lines 35-43; paragraphs bridging columns 4 and 5, columns 5 and 6, columns 14 and 15, and columns 15 and 16; Example II.

Casas *et al.* are silent about the presence of a flavorant, such as a strawberry flavorant, in their icecream or yoghurt comprising the orally administered vaccine.

However, the use of a strawberry-flavored milk or yoghurt was known and such a product was available in the art at the time of the invention. For example, patent DE 1793631 taught the routine and conventional addition of a strawberry flavor to ice-cream, yoghurt and milk drinks for the purpose of imparting strawberry taste to these foods. The patent DE 1793631 taught yoghurt

and milk drinks containing a strawberry flavoring agent (see abstract). That the strawberry flavorant used in the flavored yoghurt and milk drinks described by the patent DE 1793631 is intrinsically water soluble is implicit from the disclosure of the patent in light of what was known in the art. For instance, Shimada *et al.* expressly taught the strawberry flavorant to be water soluble (see claims and Table in columns 11 and 12, particularly line 8 in column 12).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to replace Casas's milk or yoghurt with the DE 1793631 patented strawberry-flavored milk or yoghurt to produce the instant invention, with a reasonable expectation of success. One of skill in the art would have been motivated to produce the instant invention for the expected benefit of imparting a strawberry taste to Casas's milk or yoghurt, since the use of such taste-improving fruit-flavored food products were well known in the art at the time of the invention as taught by the patent DE 1793631.

Claims 1-3, 5, 6, 29 and 30 are *prima facie* obvious over the prior art of record.

27) Claims 1-3, 5, 6, 9, 29 and 30 are rejected under 35 U.S.C § 103(a) as being unpatentable over Clements *et al.* (US 6,019,982, already of record) in view of the DE patent 1793631 and Shimada *et al.* (US 5,626,837).

Clements *et al.* disclosed a method of providing protection against an enterotoxigenic bacterial pathogen, such as, *Escherichia coli*, by administering an oral vaccine composition comprising the killed or attenuated whole cells of the pathogen and/or a mutant heat-labile enterotoxin. The vaccine comprises a microbial protective antigen such as *Escherichia coli* (a poultry pathogen), *Borrelia burgdorferi* (a canine pathogen), *Clostridium tetani*, *Salmonella typhimurium* (a poultry pathogen), *Brucella suis* (a porcine pathogen), *Leptospira icterohaemorrhagiae*, *Mycoplasma* sps. or parainfluenza virus, Reo virus, Parvo virus, or respiratory syncytial virus etc., The method is used in birds, immature and mature vertebrates, animal species, mammals and humans. The antigen composition is produced by combining the antigen(s) with a liquid pharmaceutical carrier and a palatable flavoring agent for oral administration. The vaccine is further reconstituted with a substance such as milk. See sections 5 and 5.2 of the patent, particularly in columns 9-14 and fifth and sixth full paragraphs in column 4. That Clements' 'birds' are inclusive of poultry and that Clements' 'vertebrates' or 'animal species' are inclusive of swine or dogs is inherent from the

teachings of Clements *et al.* since it is well known in the art that Clements' antigens, such as, *Salmonella typhimurium* or *Escherichia coli* are art-known poultry, swine or canine pathogens, *Borrelia burgdorferi* is an art-known canine pathogen, and *Brucella suis* is a art-known swine pathogen.

Clements *et al.* are silent about the presence of a flavorant, such as a strawberry flavorant, in their oral composition reconstituted with milk.

However, the use of a strawberry-flavored milk or yoghurt was known and available in the art at the time of the invention. For example, patent DE 1793631 taught the routine and conventional addition of a strawberry flavor to and milk drinks to impart strawberry taste to these foods. The patent DE 1793631 taught milk drinks containing a strawberry flavoring agent (see abstract). That the strawberry flavorant used in the flavored milk drinks described by the patent DE 1793631 is intrinsically water soluble is implicit from the disclosure of the patent in light of what is known in the art. For instance, Shimada *et al.* taught the strawberry flavorant to be water soluble (see claims and Table in columns 11 and 12, particularly line 8 in column 12).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to replace Clements's milk with the DE 1793631 patented strawberry-flavored milk to produce the instant invention, with a reasonable expectation of success. One of skill in the art would have been motivated to produce the instant invention for the expected benefit of imparting a strawberry taste to Clements's milk, since the use of such taste-improving fruit-flavored food products were well known in the art at the time of the invention as taught by the patent DE 1793631.

Claims 1-3, 5, 6, 9, 29 and 30 are *prima facie* obvious over the prior art of record.

28) Claims 4, 7, 27 and 28 are rejected under 35 U.S.C § 103(a) as being unpatentable over Casas *et al.* (US 6,100,388, already of record) or Clements *et al.* (US 6,019,982, already of record) as modified by the DE patent 1793631 and Shimada *et al.* (US 5,626,837) as applied to claims 1 and 4 above, and further in view of Grieve (*Poultry Digest*, November 1992, pp. 28-32, already of record).

The teachings of Casas *et al.* or Clements *et al.* as modified by the DE patent 1793631 and Shimada *et al.* are explained above, which do not disclose the administration of the vaccine through drinking water.

However, it was routine at the time of the instant invention to carry out mass vaccination of poultry via drinking water. For instance, Grieve taught the routine, economical and time-effective mass vaccination of poultry through drinking water (see page 28).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to carry out Casas's or Clements' method of providing protection to poultry birds as modified by the DE patent 1793631 and Shimada *et al.* via drinking water vehicle as taught by Grieve to produce the instant invention with a reasonable expectation of success, since Grieve showed it to be conventional, routine, economical and time-effective to administer a vaccine to poultry birds via drinking water. Choosing one art-known administration route or vehicle over another route or vehicle would have been obvious and was well within the realm of routine experimentation. One of skill in the art would have readily understood that administration of a vaccine via drinking water for mass vaccination is a matter of convenience, economy and time effectiveness.

Claims 4, 7, 27 and 28 are *prima facie* obvious over the prior art of record.

29) Claim 10 is rejected under 35 U.S.C § 103(a) as being unpatentable over Casas *et al.* (US 6,100,388, already of record) or Clements *et al.* (US 6,019,982, already of record) as modified by the DE patent 1793631, Shimada *et al.* (US 5,626,837) and Grieve (*Poultry Digest*, November 1992, pp. 28-32, already of record) as applied to claims 1, 6 and 7 above, and further in view of Roland (US 6,399,074, already of record).

The reference of Roland is applied in this rejection because it qualifies as prior art under subsection (e) of 35 U.S.C § 102 and accordingly is not disqualified under U.S.C 103(a).

The teachings of Casas *et al.* or Clements *et al.* as modified by the DE patent 1793631, Shimada *et al.* and Grieve are explained above, which do not disclose the administration of the vaccine into the mouth through a syringe.

However, it was routine at the time of the instant invention to use a syringe for oral administration or vaccination of birds. For instance, Roland taught such a routine procedure (see lines 20-22 in column 18)

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to carry out Casas's or Clements' method as modified by the DE patent

1793631, Shimada *et al.* and Grieve in poultry using Roland's feeding syringe to produce the instant invention with a reasonable expectation of success, since Roland has shown it to be conventional and routine to administer a vaccine orally to birds using a syringe. Choosing one art-known administration method over another would have been obvious and is well within the realm of routine experimentation. One of skill in the art would have readily understood that oral administration of a vaccine using a syringe is a matter of convenience.

Claim 10 is *prima facie* obvious over the prior art of record.

30) Claim 8 is rejected under 35 U.S.C § 103(a) as being unpatentable over Clements *et al.* (US 6,019,982) as modified by the DE patent 1793631, Shimada *et al.* (US 5,626,837) and Grieve (*Poultry Digest*, November 1992, pp. 28-32, already of record) as applied to claims 1, 6 and 7 above, and further in view of Frantz *et al.* (US 5,536,496, already of record).

The teachings of Clements *et al.* as modified by the DE patent 1793631, Shimada *et al.* and Grieve are explained above, which do not disclose the administration of *Erysipelothrix rhusiopathiae*-containing vaccine.

However, Clements *et al.* taught that their vaccine may contain and be administered with any biologically relevant antigen and/or vaccine, or killed or attenuated pathogens or relevant virulence determinants (i.e., antigens) of specific pathogens. See paragraph bridging columns 9 and 10; and paragraph bridging columns 11 and 12.

Frantz *et al.* disclosed an *Erysipelothrix rhusiopathiae* bacterin or vaccine which is administered by any mode of administration or by any suitable route. The vaccine protected pigs from a challenge infection. See columns 20 and 21; see first full paragraph in column 5; and paragraph bridging columns 5 and 6.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use Frantz's *Erysipelothrix rhusiopathiae* bacterin or protective vaccine in Clements' method as modified by the DE patent 1793631, Shimada *et al.* and Grieve to produce the instant invention with a reasonable expectation of success, since Clements *et al.* expressly taught that any biologically relevant antigen and/or vaccine, or killed or attenuated pathogens or relevant virulence determinants (i.e., antigens) of a specific pathogen can be used in their method. Given the teaching of Frantz *et al.* that their *Erysipelothrix rhusiopathiae* bacterin or protective vaccine is

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administered by any mode of administration or by any suitable route, one of skill in the art would have been motivated to produce the instant invention for the expected benefit of providing protection against *Erysipelothrix rhusiopathiae* disease in pigs or immature piglets.

Claim 8 is *prima facie* obvious over the prior art of record.

Relevant Prior Art

31) The prior art made of record and not relied upon currently in any of the rejections is considered pertinent to Applicants' disclosure:

- Chen *et al.* (US 2003/0068378 A1, filed January 1999) taught that the cherry, strawberry and watermelon flavoring agents are water soluble extracts (see section 0040).

Remarks

32) Claims 1-10 and 27-30 stand rejected.

33) Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

34) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1 (CM1). The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone number is (703) 308-4242, which receives papers 24 hours a day and seven days a week. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

35) Any inquiry concerning this communication or earlier communications from the Examiner

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should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

June, 2003


S. DEVI, PH.D.
PRIMARY EXAMINER